MAR 2 0 2002

510(k) SUMMARY

K020590

Model 733HC Vacuum/Gravity Steam Sterilizer

Submitted by:	Getinge/Castle Inc. 1777 E Henrietta Road Rochester, NY 14623-3133
Contact Person:	Frederick R. Catt Senior, Regulatory Compliance Engineer Phone: (585) 272-5013 Fax: (585) 272-5299
Date prepared:	March 15, 2002
Proprietary Name:	Model 733HC Vacuum/Gravity Steam Sterilizer
Common Name:	Steam Sterilizer
Device Classification:	Steam Sterilizer (80 FLE) Class II, as listed per 21 CFR 880.6880
Predicate Device:	Castle® 400HC/500HC Series Steam Sterilizer [K012573]

Description of Device:

The 733HC Vacuum/Gravity Steam Sterilizer is intended for use in hospital and health care facilities. The product incorporates a medium sized chamber and has the same control system and offers similar overall features as those on the 400HC/500HC Series Steam Sterilizers. These include:

- additional functionality
- ease of use to the end user
- large color display that will allow the user to choose from the entire list of available cycles
- allows renaming and re-sequencing of sterilization cycles.

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The full list of available cycles is as follows:

Table 1. Model 733HC Vacuum/Gravity Steam Sterilizer Cycle and Load Chart

Cycle Type	Factory Set Cycle P#	Factory Settings			Load Configuration[2]	
		Exposure Temp.	Exposure Time	Dry Time[1]		
PREVAC1 (vac)	P1-P5	275°F (135°C)	3 min.	16 min.	Wrapped instrument trays, up to 16 lbs., per tray • 39" length – 10 max. • 53" length – 15 max. • 61" length – 20 max.	Fabric packs • 39" length – 24 max. • 53" length – 32 max. • 61" length – 48 max.
PREVAC2 (vac)	P6-P8	275°F (135°C)	3 min.	3 min.	Fabric packs • 39" length 24 max. • 53" length 32 max. • 61" length 48 max.	
Bowie-Dick Test (vac)	P9	273°F (134°C)	3.5 min	0 min.	S.M.A.R.T. Pack or equivalent (1 max.)	
GRAVITY1 (grv)	P10-P13	250°F (121°C)	30 min.	30 min.	Wrapped instrument trays, up to 16 lbs., per tray • 39" length 10 max. • 53" length 15 max. • 61" length 20 max.	Fabric packs • 39" length 24 max. • 53" length 32 max. • 61" length 48 max.
GRAVITY2 (grv)	P14-P16	275°F (135°C)	10 min.	30 min.	Wrapped instrument trays, up to 16 lbs., per tray • 39" length 10 max. • 53" length 15 max. • 61" length 20 max.	Fabric packs • 39" length 24 max. • 53" length 32 max. • 61" length 48 max.
Flash 3+[2] (f 3)	P17	275°F (135°C)	3 min.	10 sec.[3]	• Unwrapped non-porous instrument trays (3 trays maximum; up to 16 lbs., per each tray.)	
Liquids1 (liq)	P18	250°F (121°C)	30 min.	0.75 psi/min.[4]	Up to 250 mL containers • 39" length 384 max. • 53" length 544 max. • 61" length 672 max.	
Liquids2 (liq)	P19	250°F (121°C)	45 min.	0.75 psi/min.[4]	Up to 1000 mL containers • 39" length 112 max. • 53" length 154 max. • 61" length 196 max.	
Vacuum Leak Test[5] (lkt)	P20	268°F (131°C)	3 min.	15 min. dry 5 min. dwell 15 min. test	Empty chamber	

Notes for Table 1:

Load configurations follow AAMI Standards *ST8 Hospital Steam Sterilizers* where applicable.

1. Factory set drying time is the recommended minimum drying time. Extended drying time may be required depending on local conditions.
2. Refer to AAMI standards ST46 Good Hospital Practice: Steam Sterilization and Sterility Assurance and ST37 Good Hospital Practice: Flash Sterilization — Steam Sterilization of Patient Care Items for Immediate Use.
3. Items may NOT be dry. Dry time may be added if required.
4. Cooldown rate
5. Vacuum leak test cycle parameters are not adjustable.

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March 15, 2002

Intended Use:

Model 733HC Vacuum/Gravity Steam Sterilizers are intended for use by health care facilities and to be used to sterilize wrapped and unwrapped surgical instruments, linens and liquids (liquids not intended for direct patient contact) by means of pressurized steam.

Predicate Device

Castle® 400HC/500HC Series Steam Sterilizer [K012573].

Nonclinical Comparisons to Predicate Device

The 733HC Vacuum/Gravity Steam Sterilizer is a new model number designation to identify incorporation of our updated sterilizer control system (PACS 3000) with medium sterilizer chamber sizes and loads. The chamber cross-section dimensions are 672mm x 920mm (26.5" x 36"). Three lengths are available – 1000mm (39"), 1350mm (53") and 1550mm (61"). The 733HC sterilizer is similar to the 400HC/500HC Series Steam Sterilizer (predicate device), but with a larger chamber size and volume. Modifications made from the predicate device include:

- The sterilizer chamber sizes are larger. New sliding and slide/swing door closure designs are used, that accommodates the larger vessel opening.
- Added door key lockout type feature to prevent door movement when there is a need to enter the sterilizer chamber of the Model 733HC.
- Two cycles, Flash 10+ and PreVac 3, are not offered since they are not used with larger capacity sterilizers.
- Piping changes for incorporation with the larger pressure vessel design.
- Parameter Check feature has been added to the control system to warn an operator if changes made to a preset cycle time or temperature settings fall outside an allowable range.

Clinical Data:

No clinical data is required for this device classification submission.

Conclusion:

The 733HC Vacuum/Gravity Steam Sterilizer is a substantially equivalent device to that of the predicate device. There have been no substantial changes in technology, intended use of this device. This sterilizer meets the applicable requirements of AAMI ST8, CSA-Z314.7, GGS-1340A and GGS-1343A Standards.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 2 0 2002

Mr. Frederick R. Catt
Senior Regulatory Compliance Engineer
Getinge Castle, Incorporated
1777 East Henrietta Road
Rochester, New York 14623-3133

Re: K020590
Trade/Device Name: Model 733HC Vacuum/Gravity Steam Sterilizer
Regulation Number: 880.6880
Regulation Name: Steam Sterilizer
Regulatory Class: II
Product Code: FLE
Dated: February 20, 2002
Received: February 22, 2002

Dear Mr. Catt:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4618. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Susan Runner

for Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

MAR 2 0 2002

INDICATIONS FOR USE STATEMENT

510(k) Number: K020590

Device Name: **733HC Vacuum/Gravity Steam Sterilizer**

Indications for Use:

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4. Cooldown rate
5. Vacuum leak test cycle parameters are not adjustable.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K020590